UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)(KMW)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE OPINIONS OF WAYNE GIBSON

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I. INTRODUCTION

This Motion addresses two (2) expert reports submitted by defense expert Wayne Gibson. (**Exs. 1 & 2**.)[1] Mr. Gibson is an employee of FTI Consulting who has billed Defendants in excess of $850,000 to provide three critiques of Dr. Rena Conti's damages methodology.[2] First, Mr. Gibson argues that Dr. Conti "fails" to account for various federal program subsidies provided to plan sponsors by CMS/Medicare *post* point of sale. Not only are these post-point of sale reimbursements completely unquantified and thus hopelessly speculative, they are also clearly barred by the collateral source doctrine, and many are not even associated with valsartan prescriptions. Second, Mr. Gibson speculates that these valsartan products were "potentially" subject to Direct and Indirect Remuneration ("DIR") "offsets", but does not identify any valsartan-specific DIR. Nor can he; there is simply no such thing as valsartan DIR. Third and finally, Mr. Gibson criticizes Dr. Conti's IQVIA-based damages model by presenting misleading price comparisons to argue that IQVIA results in artificially elevated pricing for these VCDs compared to other sources of pricing information. Mr. Gibson's circular critique ignores the admitted fact that IQVIA presents what is considered the

[1] All exhibit references herein are to the Certification of John R. Davis submitted herewith.

[2] Dr. Conti's methodology is succinctly stated herein. Dr. Conti calculates damages at the point of sale based on the difference between the price at the point of sale and zero.

benchmark sales data for the pharmaceutical industry, and critical limitations in the comparator sources on which he places outsized reliance, with no reliable basis for his opinion that the IQVIA data on which Dr. Conti relies is not credible.

II. APPLICABLE LAW

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.,* 186 F.3d 412, 417-18 (3d Cir. 1999).

First, Rule 702 "requires the witness to have 'specialized knowledge' regarding the area of testimony" proffered by the witness. *Waldorf v. Shuta*, 142 F.3d 601 (3d Cir 1998). Once qualified, an "expert's opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, "the expert must have 'good grounds' for his or her belief." *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis and, "*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *Id.* at 745. Judges within this Circuit also consider how and when the methodology is used outside of litigation. *Paoli*, 35 F.3d at 742 (discussing reliability factors under

Daubert and Third Circuit case law).

Importantly, the Third Circuit has held that "[i]t is an abuse of discretion to admit expert testimony which is based on assumptions lacking any factual foundation in the record." *Steyck v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) (citing *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 & n.13 (3d Cir. 2000)). Expert testimony that is contrary to law or fact, or that seeks to misstate the applicable law to the jury, is unhelpful. *See, e.g.*, *SEC v. Ambassador Advisors, LLC*, -- F. Supp. 3d –, *5 (E.D. Pa. Dec. 21, 2021). Expert analysis also must have sufficient support in facts or data for the conclusions reached. *See, e.g.*, *Mondis Tech. Ltd. v. LG Elecs., Inc.*, No. 15-4431, 2021 WL 4077563, at *3 (D.N.J. Sept. 8, 2021). Opinions that rest on "assumptions and conclusions that are not supported by the factual record" have been excluded on the basis that it would not "aid the jury in resolving a factual dispute" because it does not "fit under the facts of the case." *Meadows*, 306 F. App'x at 790 (citing *Stecyk*, 295 F.3d at 414, and quoting *Lauria*, 145 F.3d at 599).

Furthermore, "*Daubert*'s gatekeeping requirement .... make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152

(1999)); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F.Supp.2d 584, 594 (D.N.J.2002*), aff'd,* 68 Fed. Appx. 356 (3d Cir. 2003).

III. ARGUMENT

A. Mr. Gibson's Opinions Regarding CMS/Medicare Subsidies Should be Excluded

Mr. Gibson contends that Dr. Conti's damages analysis fails to credit four (4) federal subsidies that Part D plans receive from CMS. These are the: (1) "direct subsidy" which is a prospective payment "[redacted],]" (**Ex. 3** (Gibson 9/20/23 Dep. 53:20-24)); (2) the "low income subsidy" which is a post-point of sale reimbursement made by CMS where applicable; (3) the "catastrophic phase" subsidy which is another post-point of sale reimbursement where CMS covers roughly eighty percent (80%) of the prescription payment; and (4) the "risk corridor" subsidy which is "[redacted]" and paid to cover plan costs that exceed certain thresholds (Gibson 9/20/23 Dep. 141:7-142:12).

First, none of these purported amounts is quantified by Mr. Gibson. Defendants hope to use Mr. Gibson's vague analysis to allow the jury to speculate about amounts by which to diminish the damages. The failure of his methodology to present a quantification of the offset he seeks to apply renders the entire analysis hopelessly speculative, and methodologically unsound. *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d at 742.

Mr. Gibson also confirmed that none of these four subsidies affect the Part D Plan's obligations at the point of sale, and that he was not offering any opinion that the Part D Plan did not incur the cost at the point of sale. (**Ex. 4** (Gibson 2/5/24 Dep. 85:21-86:10 (confirming that all these subsidies are "[redacted]"); 110:8-20 (same); *see also* Gibson 9/20/23 Dep. 166:18-167:1 [redacted]")). Thus, this opinion does not even fit with the opinion to which he purports to respond.

1. The Collateral Source Doctrine Bars Defendants from Claiming Credit for CMS Subsidies Paid to Part D Plans

Mr. Gibson likewise confirmed – albeit reluctantly – that he is not offering any opinion that Defendants would be entitled to a single penny of these subsidy amounts if credited against Dr. Conti's damages model. (Gibson 9/20/23 Dep. 144:11-149:16.) That is because these CMS subsidies do not involve manufacturers at all. They are exclusively between CMS and Part D Plans. And although clearly advised to avoid doing so, **Mr. Gibson could not help but admit the obvious: crediting these subsidies against Dr. Conti's damages model provides an "offset" to which Defendants are not entitled**. (Gibson 9/20/23 Dep. 161:3-14 (Gibson twice referring to these CMS subsidies as [redacted]").)

The collateral source doctrine bars Defendants from arguing to the jury that these CMS Part D program subsidies reduce their liability. As the Third Circuit has recognized, "collateral benefit[s] [are] ordinarily not deducted from a plaintiff's recovery. Under the collateral benefit rule, payment which a plaintiff receives for his or her loss from another source is not credited against the defendant's liability[.]" *Craig v. Y & Y Snacks, Inc.*, 721 F.2d 77, 83 (3d Cir. 1983) (finding that unemployment benefits received by the plaintiff should not reduce plaintiff's recovery against the wrongful termination defendant and citing authorities). More specifically, these exact Medicare subsidies have been held to be subject to the collateral source rule. *In re HIV Antitrust Litig.*, No. 19cv2573, 2023 WL 3603732, at *2-3 (N.D. Cal. May 23, 2023) ("Defendants shall not be permitted to raise Medicare payments as a set-off to Plaintiffs' damages."); *In re Zetia (Ezetimibe) Antitrust Litigation*, No. 18-md-2836, 2023 WL 3064462, at *5 (E.D. Va. Apr. 18, 2023), (precluding evidence and argument to the jury (including opinions of Dr. Lauren Stiroh, one of Defendants' experts here) about Medicare monies under the collateral source rule and that it would only mislead and confuse the jury); *accord Titchnell v. United States*, 681 F.2d 165 (3d Cir. 1982) (Medicare payments are subject to collateral source rule).

As set forth by Dr. Conti in her expert reports explaining her damages methodology, TPP class members were injured and incurred economic damages at

the point of sale. The fact that TPPs may have later received hopelessly unquantified "after-the-point-of-sale adjustments" should not inure to the wrongdoers' benefit. Accordingly, Mr. Gibson's testimony would be unhelpful to the jury since it improperly requests the jury to reduce TPP class members' damages based on speculative, unquantified offsets, in violation of the collateral source rule.

2. The "Direct Subsidy" and the "Risk Corridor Subsidy" Are Admittedly Unrelated to Payments by TPPs for At Issue VCDs, and Mr. Gibson Cannot Offer Any Offset Calculation for the Low Income and Catastrophic Phase Subsidies

Even if the Court were to find that these CMS subsidies are not subject to the collateral source doctrine, at least two of these unquantified four subsidies are categorically unrelated to reimbursement for VCD prescriptions therefore simply not subject to any possible damages adjustment.

Mr. Gibson testified that the "direct subsidy" is a general "[redacted]t." (Gibson 9/20/23 Dep. 53:20-24.) CMS pays the direct subsidy prospectively based on the Part D Plan's bid for the upcoming calendar year. (Gibson Rep. ¶ 30.) Because it is a general subsidy, Mr. Gibson conceded that [redacted]**" and thus is not directly linked to any valsartan prescriptions**. (Gibson 9/20/23 Dep. 97:21-98:1.)

Similarly, the "risk corridor subsidy" is essentially a truing up of the benefit at the end of the calendar year where either the Part D Plan pays money back to CMS or vice versa depending on whether the Part D Plan's total expenditures met or exceeded a set target. (Gibson 9/20/23 Dep. 140:22-142:12.) **Mr. Gibson admitted that the risk corridor subsidy is "[redacted]" and has no direct relation to valsartan prescriptions**. (Id.)

Because these two subsidies are not directly related to payments for VCDs, Mr. Gibson's opinion that Defendants' liabilities should be reduced lacks any factual foundation in the record. The Court should exclude Mr. Gibson's opinions.

Moreover, as stated above, as with the full list of purported offsets, Mr. Gibson offers no calculations for what these offset amounts would be for any of those identified. Accordingly, since Mr. Gibson has not presented a calculation quantifying the purported offsets, he lacks a reliable methodology - leaving it to the jury to speculate and make up the amount of the purported offsets. That of course would be impermissible. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 742.

B. <u>Mr. Gibson's DIR Offset Argument Should Likewise Be Excluded</u>

Mr. Gibson also critiques Dr. Conti for failing to credit offsets for direct and indirect remuneration ("DIR") amounts allegedly received by TPP class members for valsartan. However, Mr. Gibson utterly fails to identify any such DIR amounts related to valsartan. Nor can he because valsartan DIR simply does not exist.

Thus, in addition to the exclusion based on the collateral source doctrine where any purported DIR amounts were not directly between TPP class members and TPP Trial Defendants as set forth *supra*, this opinion too is without a reliable basis.

DIR amounts are not attributable to particular drugs and any argument for a "valsartan DIR offset" would be hopelessly speculative (as defendants have not identified or quantified any such DIR). In fact, the factual record establishes that there is no such thing as valsartan DIR. [redacted]

Mr. Gibson's DIR opinions are thus flawed in multiple respects. First, he concedes that he has no actual evidence of any DIR amounts from which to argue for this offset. (Gibson Rep. Opinion E Header (referring to "potential" DIR).) Thus, Mr. Gibson's DIR opinion should be excluded as lacking any reliable foundation in the factual record. Second, Mr. Gibson offers no methodology to account for how any non-existent valsartan DIR should be calculated as an offset (as is Defendants' burden), thus leaving the jury to speculate and make up the

numbers. As the retail pharmacy defendants themselves state, "[redacted]]" The Court should exclude Mr. Gibson's DIR opinion as lacking any basis in the factual record and lacking any methodology, failing to give the jury a remotely concrete basis to calculate this amount even if it actually existed.

C. Mr. Gibson's Critique of IQVIA Ignores Critical Information, and is Premised on Circular Logic

Mr. Gibson's final critique of Dr. Conti's damages methodology is premised on his unsupported belief that IQVIA's pricing data fatally overstates the actual prices for the at-issue VCDs.

In support of this theory, Mr. Gibson attempts to interpret a single unauthenticated hearsay email purportedly sent by an employee of IQVIA to a third party later forwarded to Mr. Gibson by Defendants' counsel. (Gibson 9/20/23 Dep. 189:1-12). The email is not admissible based on basic concepts of authenticity and hearsay, aside from its lack of usefulness and fit.

Specifically, the email in question states that a "notable" portion of pharmacies may report the "list price" of the drugs. However, Mr. Gibson admitted that he had no understanding of what "notable" or "list price" meant and that he chose not to find out by, for example, ever communicating with anyone at IQVIA. (Gibson 2/5/24 Dep. 23:23-25:10, 28:3-25).

Accordingly, Mr. Gibson's opinion that IQIVA is unreliable because some unknown "notable" portion of pharmacies may report "list price" is untethered to any actual methodology that would quantify or provide the specificity needed for it to be helpful to a jury. He simply relied on a purported hearsay email forwarded to him by counsel to which he had no connection and made no attempt to understand. And to cap it off, Mr. Gibson admitted that he could not identify a single instance where a pharmacy reported "list price" to IQVIA where that was not the actual price at the point of sale.[3] (Gibson 2/5/24 Dep. 25:11-26:25). Thus, this is yet another fertile area for jury speculation.

Standing against this, and not accounted for by Mr. Gibson, is a wealth of evidence that IQVIA is the "gold standard" for pricing data in this industry. Mr. Gibson admitted that he did not review any testimony from the manufacturers' own witnesses on this topic. As but one example, ZHP's corporate representative Hai Wang testified that IQVIA is "[redacted]" for "[redacted]" pricing analysis. (**Ex. 7** (H. Wang 3/11/21 Day 2 Dep. 499:8-502:15); *see also* **Ex. 8** (H. Wang 3/10/21 Day 1 Dep. 48:18-49:9 ("[redacted]").).) Even defense expert Dr. Lauren Stiroh

[3] Mr. Gibson claims that is not possible, but again, he undertook zero investigation of his own aside from reviewing a single email sent by IQVIA personnel to someone else.

admitted she "[redacted]" and "[redacted]" for expert opinions she has offered. (**Ex. 9** (3/25/22 Stiroh Dep. 81:11-83:5).) Defense expert Timothy Kosty also agreed that IQVIA is the [redacted]" and "[redacted][.]" (**Ex. 10** (T. Kosty 2/24/22 Dep. 134:10-15).) Despite listing Dr. Stiroh's and Mr. Kosty's depositions in his reliance materials, Mr. Gibson made no attempt to reconcile these endorsements by *Defendants' own experts* with his outlier opinion that IQVIA is inaccurate based on a single unauthenticated email forwarded to him by defense counsel. Further, Dr. Rena Conti recently testified that IQVIA Xponent data has been relied on by more than 60 peer-reviewed publications in just the past few years alone and that this is the data Dr. Conti works with on a daily basis as an economist in public health matters unrelated to litigation or damages analyses. (**Ex. 6** (Conti 2/1/24 Dep. 94:7-21).)

Defendants may contend that Mr. Gibson's opinion is bolstered by the fact that IQVIA's reported prices (IQVIA encompasses approximately 90% of all retail transactions nationwide (R. Conti 2/1/24 Dep. 141:11-15)) are higher than those found in the pharmacy defendants' dataset and Medicare Part D summary data.

However, the pharmacy dataset and Part D summary data are smaller and more discrete datasets, and carry interpretative limitations, none of which were considered by Mr. Gibson, who chose to ignore the key factors that result in different reported prices. For example, the pharmacy data produced by the

pharmacy defendants exclusively represents prescriptions filled at large chain and grocery store pharmacies. It is well-established that there is substantial pricing variability for generic drugs based exclusively on pharmacy choice, and peer-reviewed literature shows that large chain and grocery store pharmacies carried the lowest point of sale costs by a significant margin. (*See, e.g.*, R. Conti 2/1/24 Dep. 131:17-22 ("Big box stores and grocery stores have been shown in peer-reviewed publications to have lower prices … on average than mom-and-pop stores.").) Critically, when confronted with this factor during his deposition, Mr. Gibson agreed to the concept of "[redacted]" including based on pharmacy type (Gibson 2/5/24 Dep. 50:16-51:2), and further admitted not doing "[redacted]." (Id. at 51:11-12). In other words, he admitted that his methodology was hopelessly deficient since it ignored important concepts that he agrees are directly relevant and correct, and were factored in by Plaintiffs' expert. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012) ("As we have made clear, the reliability analysis [required by *Daubert*] applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, [and] the link between the facts and the conclusion." (internal quotations and citation omitted)).

This is a consequential difference. Mr. Gibson admitted that hundreds of millions of quantities accounted for in the IQVIA data are not accounted for in the narrower pharmacy dataset. (Gibson 2/5/24 Dep. 142:5-144:11). For Teva, for example, the pharmacy datasets only capture approximately 39% of the total quantities as reported by IQVIA. (Gibson 2/5/24 Dep. 52:1-12.) Mr. Gibson made no attempt to understand how the unaccounted for 61% of Teva quantities (about 100 million Teva quantities) were priced. (Gibson 2/5/24 Dep. 53:1-20). Similarly, for plain valsartan sold by ZHP/Solco, the pharmacy datasets only capture approximately 60% of the IQVIA-reported quantities, which Mr. Gibson admitted leaves nearly 300 million quantities unaccounted for. (Gibson 2/5/24 Dep. 143:19-144:11.)

Crucially, Mr. Gibson ignores the observation that as the pharmacy data begins to approximate IQVIA in terms of quantities, the reported prices become much more consistent, suggesting that the difference in pricing is attributable simply to the fact that IQVIA is a much more robust and complete set of data. Unlike Teva where the pharmacy data only captures 39% of the IQVIA-reported quantities, for Torrent it captures approximately 75%. As remarked and noted by Dr. Conti, the pharmacy dataset pricing and IQVIA pricing for Torrent is much more aligned (with average prices often only differing by a few pennies). (R. Conti 2/1/24 Dep. 76:8-77:21.) The same is true for ZHP/Solco valsartan-HCTZ, where

the pharmacy datasets capture a little more than 70% of the IQVIA-reported quantities. The pharmacy dataset pricing is very much aligned with IQVIA pricing for ZHP/Solco valsartan-HCTZ (again usually within a few pennies). (**Ex. 11** (Conti Supp'l Rep. 12/1/23, Table 7).)

In addition, Mr. Gibson also failed to account for the fact that the pharmacy data contains a significantly greater percentage of mail order prescriptions than are reported in the much larger IQVIA sample. (Gibson 2/5/24 Dep. 104:9-10 (agreeing with disparity), 132:10-134:16 (did not do any analysis of pricing disparities in mail order versus retail).)

Mr. Gibson also compares the IQVIA prices to lower Medicare Part D prices, but concedes that he does not believe the Medicare Part D data is reliable to extrapolate general market pricing because it is limited to Part D prescriptions (which account for only roughly half of the total prescriptions). (Gibson 2/5/24 Dep. 41:2-42:4.) And indeed, Mr. Gibson made no effort to compare Part D pricing to commercial pricing to see if there were any differences. (Gibson 2/5/24 Dep. 43:1-12). The methodological flaws are too many to overcome.

Ultimately, Mr. Gibson's flawed analysis can be summed up as follows: because IQVIA reported prices look different at first blush from the retailers' more limited databases, IQVIA must be incorrect. However, Mr. Gibson failed to dig

any further. The Court should exclude his scratch the surface analysis as unreliable and lacking any rigorous methodology.

IV. CONCLUSION

For the foregoing reasons, Mr. Gibson should be excluded from offering his opinions.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 12, 2024, a true and correct redacted copy of the foregoing was filed and served via the Court's CM/ECF system, and an undredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch
David J. Stanoch